

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEMS
PRODUCTS LIABILITY LITIGATION

Master File No. 2:12-MD-02327

THIS DOCUMENT RELATES TO:
CAROLYN LEWIS, ET AL. V ETHICON, INC.
Case No. 2:12-CV-04301

MDL No. 2327

JOSEPH R. GOODWIN
U.S. DISTRICT JUDGE

PLAINTIFF CAROLYN LEWIS'S BRIEF ON DIRECTED VERDICT ISSUES

Plaintiff Carolyn Lewis respectfully submits this brief in response to the Court's request for briefing on the issues of design defect and specific causation. There are essentially three inquiries that the jury must undertake as part of Mrs. Lewis's design defect claim: whether the TVT product is unreasonably dangerous, whether the TVT was the "producing cause" of her injuries, and whether there was a safer alternative design that would have significantly reduced her risk of injury.

As explained below, Plaintiff has made a prima facie showing as to each of these elements. The issue of whether the product is unreasonably dangerous is determined under a risk-utility balancing test that is generally a jury question. Plaintiff simply must put forth some evidence of the risk, and she has clearly done so, based on expert testimony and the admissions of defense witnesses.

As to the second element, causation, Texas common law only requires that Plaintiff connect the product to the injury, and Plaintiff has done so. Philippe Zimmern, M.D., has directly testified that the TVT caused Mrs. Lewis's pain and dyspareunia. And even if the Court requires a showing that particular defects in the mesh caused Mrs. Lewis's injuries, she has produced ample evidence that there is a connection between the design flaws identified by the

Plaintiff—such as the use of heavyweight, large-pore mesh and the use of mechanical cutting—are directly related to Mrs. Lewis’s injuries.

Finally, Plaintiff has produced substantial evidence on the existence of a safer alternative design. As explained below, Texas law requires only more than a “scintilla” of evidence to submit the safer alternative design question to the jury, and the jury is permitted to make inferences from the evidence. A lightweight, larger-pore mesh; a mesh product cut by a laser, not mechanically; the burch colposuspension procedure using sutures; and the use of a lighter, more absorbable material than Prolene would all be safer alternative designs to the TVT.

For these reasons, Plaintiff’s design defect claim should go to the jury.

I. Rule 50(a) Standard

If Defendant moves for a directed verdict, its motion will be governed by Rule 50(a). The rule states that if “a party has been fully heard on an issue during a jury trial and the court finds that a reasonable jury would not have a legally sufficient evidentiary basis to find for the party on that issue, the court may resolve the issue against the party.” Fed. R. Civ. P. 50(a)(1). This rule requires that the Court give Mrs. Lewis, as the non-movant, “the benefit of every reasonable inference that could be drawn from the evidence, neither weighing the evidence nor assessing its credibility.” *Sales v. Grant*, 158 F.3d 768, 775 (4th Cir. 1998).

II. Plaintiff Has Clearly Made the Minimal Necessary Showing as to Whether a Reasonable Jury Could Conclude That the Risks of the TVT Outweigh the Utility.

To establish a design defect, Plaintiff convince the jury that the product at issue was unreasonably dangerous, that it was the producing cause of Plaintiff’s injuries, and that there was a feasible safer alternative design that would have significantly reduced the risk that she would be injured by the product. Plaintiff will address each of these three issues separately in this brief, beginning with the risk-utility balancing test. Plaintiff has put forth far more than sufficient

evidence that the TVT product presents risks to patients, thereby allowing the jury to conclude that the product is “unreasonably dangerous.”

A. Legal Standard

The first aspect of proving a design defect under Texas law is proving that the product was unreasonably dangerous. Texas courts employ a five-factor balancing test, as follows:

- (1) the utility of the product to the user and to the public as a whole weighed against the gravity and likelihood of injury from its use;
- (2) the availability of a substitute product which would meet the same need and not be unsafe or unreasonably expensive;
- (3) the manufacturer’s ability to eliminate the unsafe character of the product without seriously impairing its usefulness or significantly increasing its costs;
- (4) the user’s anticipated awareness of the dangers inherent in the product and their avoidability because of general public knowledge of the obvious condition of the product, or of the existence of suitable warnings or instructions; and
- (5) the expectations of the ordinary consumer.

Am. Tobacco Co., Inc. v. Grinnell, 951 S.W.2d 420, 432 (Tex. 1997).

“Generally, unreasonable dangerousness is a question of fact for the jury. It only becomes a matter of law if reasonable minds cannot differ.” *Goodner v. Hyundai Motor Co., Ltd.*, 650 F.3d 1034, 1040 (5th Cir. 2011). “Evidence on the five factors may be presented to the jury, but the factors themselves are not set out as a definitional requirement of design defect.” *Id.* Thus, a plaintiff does not need evidence on all factors. *See Bryant v. Giacomini, SPA*, 391 F. Supp. 2d 495, 503 (N.D. Tex. 2005) (because plaintiff produced evidence as to the first three factors, reasonable minds could differ as to the outcome of the balancing test).

B. A Variety of Documents and Testimony Describe the Risks Associated with the TVT.

The Court should have little difficulty in concluding that Plaintiff has produced sufficient evidence to submit this issue to the jury. In particular, Plaintiff has produced ample evidence of

the TVT's risks. The testimony of expert Bruce Rosenzweig alone should be sufficient to create a fact issue as to the risk-utility test. Dr. Rosenzweig, a urogynecologist, testified that he stopped using the TVT based on his own balancing of the risks and utility of the product.¹ He further testified as to various risks associated with the TVT:

- Dr. Rosenzweig has had to remove the TVT from approximately 30 women because of complications, such as pelvic pain, painful sex, and urinary retention.²
- He has observed numerous issues with meshes he has explanted, including scarring and that the explants "looked smaller, narrower, shrunken, if you will, and there were other times where the mesh was cracked, it was broken, and ... it looked beaten up."³
- He has observed curling or roping of the mesh, which slows down the normal flow of urine.⁴
- He opined that the TVT shrinks as much as 50 percent, which leads to pain by creating tension and by drawing nerves in.⁵
- Based on both his literature review and his clinical experience, he testified that when the mesh is machine cut, small particles can fall off the mesh and cause painful sex.⁶

Dr. Rosenzweig is not alone in identifying TVT risks. Dr. Howard Jordi, another expert, opined that the mesh in the TVT's surface cracks, that the mesh degrades in the body, and that these phenomena continue as long as the mesh is in the body.⁷ Dr. Bernd Klosterhalfen, a non-retained expert, observed that the degradation of the Prolene mesh used in the TVT causes a chronic inflammatory response in the body.⁸ He also observed that nerve tissue can become trapped in the scar tissue caused by this foreign body reaction, which leads to chronic pain.⁹

¹ Trial Tr. Day 2 at 65:13-62:2.

² *Id.* at 66:16-67:4.

³ *Id.* at 70:25-71:9.

⁴ *Id.* at 75:4-6; 75:17-76:3.

⁵ *Id.* at 78:15-79:20.

⁶ *Id.* at 99:23-100:12.

⁷ Trial Tr. Day 3 at 42:12-43:1.

⁸ Klosterhalfen Dep. at 74:06-75:01.

⁹ *Id.* at 89:08-15.

Plaintiff's experts further described the TVT design characteristics that have caused these clinical problems for patients. One important flaw with the TVT's design is that it is a heavyweight, small-pore mesh.¹⁰ As Dr. Klosterhalfen described, large-pore meshes have better biocompatibility than the TVT, and thus there is less fibrotic reaction.¹¹ In comparing the Prolene mesh used in the TVT to a light-weight, large-pore mesh used in a product called Vypro, Dr. Klosterhalfen noted that the small-pore mesh had much more scar tissue.¹² That scar tissue, in turn, causes shrinkage as the body tries to remove the scar tissue.¹³ The scar tissue can then entrap nerves, causing chronic pain, as described above.¹⁴ Thus, Dr. Klosterhalfen testified that due to the lesser fibrotic reaction seen with lightweight, large-pore meshes, there is less stiffening, less shrinkage, and "these patients have a better comfort," with less chronic pain.¹⁵

Another design flaw is that the mesh is cut mechanically, rather than being cut with a laser. Dr. Rosenzweig described the process of cutting the mesh mechanically as, "it's like taking a paper cutter and cutting the segments of mesh, or a guillotine device is maybe a better way of putting it."¹⁶ He then testified that laser-cutting the mesh would prevent some of the problems caused by mechanically cutting the mesh, such as roping, curling, flaking and particle loss.¹⁷ Ethicon also took note of this same phenomenon. Gene Kammerer, an engineering fellow at Ethicon, was asked about an Ethicon study that stated, "it is of utmost importance that the mesh is cuttable and that it does not fray or release particles after cutting. The small particles

¹⁰ *Id.* at 51:23-25.

¹¹ *Id.* at 71:18-24.

¹² *Id.* at 83:01-08.

¹³ *Id.* at 83:24-84:06.

¹⁴ *Id.* at 88:08-15.

¹⁵ *Id.* at 42:06-20.

¹⁶ Trial Tr. Day 2 at 61:19-22.

¹⁷ *Id.* at 85:18-25.

migrate and cause pain during intercourse.”¹⁸ He also discussed his own study from April 2006, in which he concluded that laser-cut mesh “functions better” than mechanically cut mesh, because there is less fraying, particle loss, roping, and permanent narrowing of the mesh with laser cutting.¹⁹ A 2005 e-mail from Allison London Brown, a product director for Ethicon, stated that the mechanically cut mesh “is perceived by some physicians as inferior and we do get a high number of complaints on linting and roping (mesh particles falling off and the material stretching to the point of being a string).”²⁰

There is additional evidence of the TVT’s risks, but the evidence above is more than sufficient to avoid a directed verdict. Plaintiff also notes that the discussion below with regard to safer alternative design provides evidence as to prongs 2 and 3 of the risk-utility test. That test puts both sides’ evidence on a scale, and right now there is no evidence on the Defense side. Thus, Plaintiff merely needs to put something on her side of the scale, and she has done so.

III. Plaintiff Has Raised a Jury Question as to Causation, Regardless of Whether She Must Describe a Particular Mechanism of Harm.

For the reasons described below, Plaintiff has produced both direct and circumstantial evidence from which a reasonable jury could conclude that the TVT caused Mrs. Lewis’s injuries—and, if necessary, that the defects identified by Plaintiff caused her injuries.

A. Legal Standard

“[C]ausation generally is a question of fact for the jury.” *Goodner*, 650 F.3d at 1044 (applying Texas law). A court should grant judgment as a matter of law as to causation only “if all the facts and inferences point so strongly against causation that no reasonable jury could find causation.” *Id.* “[C]ausation need not be supported by direct evidence.” *Id.*

¹⁸ Kammerer Dep. at 190:11-18 and Exhibit 3428, p. 20.

¹⁹ *Id.* at 214:01-23.

²⁰ Brown May 06, 2005 e-mail, Plaintiff’s Exhibit 3162.

“Circumstantial evidence and reasonable inferences therefrom are a sufficient basis for a finding of causation.” *Id.*

In its ruling as to the impact of Tex. Civ. Prac. & Rem. Code § 82.005, this Court held that the Plaintiffs’ design defect claim arises under the common law. (*See* Mem. Op. & Order, Doc. No. 247, at p. 3 (stating the Court’s analysis was based upon “the common law as it existed before the 1993 enactment of Section 82.005”). The statute—and cases applying the statute—describe the causation inquiry as whether “the defect was a producing cause of the personal injury.” Tex. Civ. Prac. & Rem. Code § 82.005(a)(2). But the common law styling is slightly different. As stated by the Texas Supreme Court, “[u]nder traditional products liability law, the plaintiff must prove the defendant supplied the product that caused the injury.” *Firestone Steel Products Co. v. Barajas*, 927 S.W.2d 608, 614 (Tex. 1996) (emphasis added). *See also* 59 Tex. Jur. 3d Products Liability § 49 (stating that “products liability imposes strict liability on the manufacturer of an unreasonably dangerous product that is a producing cause of a plaintiff’s injuries”) (emphasis added). Thus, Plaintiff must prove that the TVT caused her injuries.

The applicable causation standard is “producing cause,” which means a cause that is “a substantial factor in bringing about an injury, and without which the injury would not have occurred.” *Ford Motor Co. v. Ledesma*, 242 S.W.3d 32, 46 (Tex. 2007); *see also Royal Globe Ins. Co. v. Suson*, 626 S.W.2d 161, 162-63 (Tex. App. 2 Dist. 1981) (using the term “producing cause” for a common-law claim). In a common-law case involving a medical device, the Texas Court of Appeals stated that “[i]t was not essential that the plaintiff identify the specific engineering or structural cause of the defect.” *V. Mueller & Co. v. Corley*, 570 S.W.2d 140, 143 (Tex. Ct. Civ. App. 1978).

B. Dr. Zimmern testified that the TVT caused Mrs. Lewis's injuries.

If the Court agrees that Plaintiff simply must show that the defective TVT product caused Mrs. Lewis's injuries, then the analysis should be short and simple. Philippe Zimmern is a urologist who has ample experience with performing explants of failed mesh products from the pelvic floor.²¹ He partially explanted the TVT from Mrs. Lewis.²² He agreed to answer questions to a reasonable degree of medical probability.²³ Dr. Zimmern clearly opined that the TVT caused Mrs. Lewis's pain, as seen in the following exchange:

Q. All right. In your care and treatment of Ms. Lewis, did you diagnose a cause of the pain and the dyspareunia Ms. Lewis was experiencing before the operation?

A. Yeah. I mean, she definitely had pain on examination where the tape was, so the answer is yes.

Q. And so I understand your testimony, did you diagnose, as part of your care and treatment of Carolyn Lewis, what the cause of the pain and dyspareunia was?

A. The cause being the presence of the tape. By which mechanism in the tissue she hurts, that, I don't know.²⁴

Dr. Zimmern also stated that it was not a difficult diagnosis to make.²⁵ And though he could not pinpoint a precise mechanism, he did use a differential diagnosis to rule out certain causes of the pain, such as infection and erosion.²⁶

If the Court agrees that Plaintiff simply must prove that the defective TVT caused Plaintiff's injuries, then Dr. Zimmern's testimony alone is sufficient. This Court has previously held, in a post-trial order following the *Cisson* trial, that "the plaintiffs were not required to separate the alleged defects as Bard now attempts to do." *Cisson v. C.R. Bard, Inc.*, 2:11-cv-

²¹ Zimmern Dep. at 67:05-07; 84:12-85:14.

²² *Id.* at 83:20-23.

²³ *Id.* at 71:18-21.

²⁴ *Id.* at 95:04-18.

²⁵ *Id.* at 96:10-14.

²⁶ *Id.* at 95:25-96:09.

00195, 2013 WL 5700513, at *4 (S.D. W. Va. Oct. 18, 2013). As noted, Texas law does not require that the plaintiff identify the specific product defect that caused her injuries. *V. Mueller & Co*, 570 S.W.2d at 143. Thus, Dr. Zimmermann's diagnosis, as a non-retained expert, is enough to create an issue of fact as to whether the TVT caused Mrs. Lewis's injuries, as he says it did. Plaintiff is not required to identify a precise mechanism for her injuries.

C. Expert Testimony and Other Evidence Ties the TVT Defects to Mrs. Lewis's Injuries.

Alternatively, if the Court requires that Plaintiff connect the TVT's defects to her injury, Mrs. Lewis has put on sufficient evidence to make that connection. As discussed by the Fifth Circuit in *Goodner*, expert testimony is not necessarily needed on the ultimate issue, so long as sufficient expert testimony is given on the scientific or technical aspects of the case, such that the jury can make a reasonable inference as to the ultimate issue. *See Goodner*, 650 F.3d at 1044 (allowing verdict to stand, even though plaintiff's expert was not allowed to testify to ultimate issue, because there were "not enough inferences pointing against causation here to support overturning the jury verdict"). Here, Plaintiff has provided ample evidence from which a reasonable jury could conclude that the mesh's large pore size, or the fact that it was mechanically cut, caused Mrs. Lewis's injuries.

Two experts, Dr. Jordi and Dr. Uwe Klinge, testified as to Mrs. Lewis's TVT explant. Dr. Jordi testified that the mesh degraded in Mrs. Lewis's body, and the remaining mesh will continue to do so.²⁷ Dr. Klinge testified that he observed inflammation, that he observed scar tissue covering the pores, and that this fibrotic bridging is often associated with chronic pain.²⁸ These indications seen with Mrs. Lewis's explant match the problems with heavyweight, small-pore meshes described by Dr. Klosterhalfen. As he explained, with small pores, there is greater

²⁷ Trial Tr. Day 3 at 59:06-25.

²⁸ Trial Tr. Day 4 at 77:11-20; 78:03-18; 80:1-9.

opportunity for foreign body response, which causes scar tissue.²⁹ Scar tissue causes shrinkage, and shrinkage causes pain.³⁰ More specifically, Dr. Klosterhalfen described how scar tissue and shrinkage can lead to nerve entrapment.³¹ Dr. Klinge observed this exact phenomenon in analyzing Mrs. Lewis's explant. He observed that the mesh had folded and deformed, that scar tissue had formed, and that nerves had become entrapped in the scar tissue.³² Such entrapment of nerves causes chronic pain.³³ These observations match Mrs. Lewis's testimony that she was suffering from chronic pain and dyspareunia after being implanted with the TVT.³⁴

In addition, the evidence supports an inference that the mesh being mechanically cut contributed to Mrs. Lewis's pain and caused her urinary retention. In addition to her pain, Mrs. Lewis was diagnosed as having "voiding dysfunction with slow stream," also known as urinary retention.³⁵ Dr. Rosenzweig explained how mechanically cut mesh leads to urinary retention. He discussed an internal Ethicon document, written by 36-year employee Dan Smith, explaining that a sling using laser-cut mesh "[h]as less potential to cause retention."³⁶ He further described how mesh that curl or ropes—as seen due to the mechanical cutting—can "form a point area." This point then obstructs the urethra and prevents the free flow of urine.³⁷

Finally, Dr. Klinge testified that he observed a loose particle in examining Mrs. Lewis's explant—the type of loose particle that one often sees flaking off of the edges of mechanically

²⁹ Klosterhalfen Dep. at 71:18-24; 83:01-08.

³⁰ *Id.* at 83:24-84:06; 88:08-15.

³¹ *Id.* at 88:08-15.

³² *Id.* at 83:3-13; 86:4-18.

³³ *Id.* at 86:16-18.

³⁴ Trial Tr. Day 5 at 42:3-11; 44:4-10.

³⁵ Zimmern Dep. at 102:17-25 and Exhibit 6 thereto.

³⁶ Trial Tr. Day 2 at 77:19-78:4.

³⁷ *Id.* at 75:17-76:3.

cut mesh.³⁸ Loose particles from the TVT are known to cause pain, including pain during intercourse.³⁹ And painful sex was one of Mrs. Lewis's primary symptoms.⁴⁰

To summarize all of this evidence:

- Experts who have studied Mrs. Lewis's explant have found signatures that match the exact symptoms she has been experiencing.
- Experts have explained the connection between the TVT's weight and pore size, and the fact that it is mechanically cut, and the problems seen with Mrs. Lewis's mesh.
- And, Mrs. Lewis's physician has testified that the TVT caused her injuries.

Combined, that evidence allows for a reasonable inference that the weight and pore size of the mesh caused a foreign body reaction, leading to scar tissue and eventually, to nerve entrapment, causing pain. In addition, the evidence allows for a reasonable inference that particles flaked off of the frayed edges of the mechanically cut mesh, causing pain for Mrs. Lewis and also causing her urinary retention. For these reasons, the Court should send the causation issue to the jury.

IV. Using Lightweight, Large-Pore Mesh; Using Laser Cutting; Using Sutures for the Burch Procedure; or Using a More Absorbable Material All Would Have Been Safer Alternative Designs to the TVT.

The final necessary aspect of Plaintiff's proof is showing that there is a safer alternative design.⁴¹ The evidence already described above as to design defect and causation bears on the safer alternative design inquiry. Plaintiff has put forth evidence of four possible design changes that would have made the product safer: using a lighter-weight, larger-pore mesh; using laser cutting instead of mechanical cutting; using sutures instead of a sling, as in the burch colposuspension procedure; and using a lighter-weight, partially absorbable material instead of

³⁸ Trial Tr. Day 4 at 84:7-13.

³⁹ Trial Tr. Day 2 at 100:4-19.

⁴⁰ Trial Tr. Day 5 at 42:3-11.

⁴¹ Plaintiff respectfully requests that the Court reconsider its decision requiring that Plaintiff prove the existence of a safer alternative design, based on the dictates of Tex. Civ. Prac. & Rem. Code § 82.005(d).

Prolene. The first two options and the fourth option could be also combined into a single safer alternative design.

A. Legal Standard

The legal standard for safer alternative design is difficult to pinpoint because Plaintiff's claim arises under the common law, and most cases just apply the statute. The statute states that a plaintiff must prove that there was an alternative design available that would have eliminated or "significantly reduced" the risk of injury without "substantially impairing" the product's utility; and it must have been "economically and technologically feasible." Tex. Civ. Prac. & Rem. Code § 82.005. The case that declared the existence of a common-law requirement did not flesh it out, stating only that the plaintiff provide evidence of a safer design "that could perform the same tasks." *Caterpillar, Inc. v. Shears*, 911 S.W.2d 379, 384 (Tex. 1995). Feasibility did factor into the common-law analysis, but it was not described as a necessary element of proof. *See Kindred v. Con/Chem, Inc.*, 650 S.W.2d 61, 62 (Tex. 1983) (stating that "feasibility is a relative, not an absolute concept; the more scientifically and economically feasible the alternative was, the more likely that a jury may find that the product was defectively designed").

The standard for submitting the issue of safer alternative design to the jury is that Plaintiff must put forth "more than a scintilla" of evidence "of the existence of a safer alternative design." *Gen. Motors Corp. v. Burry*, 203 S.W.3d 514, 536 (Tex. App.—Fort Worth 2006). As with the causation inquiry, the jury is permitted to draw reasonable inferences. *See Bryant*, 391 F. Supp. 2d at 502.

B. Plaintiff Has Put Forth Evidence Supporting Four Safer Alternative Designs.

The analysis above explains in some detail two of the four alternative designs proposed by Plaintiff: a sling with lightweight, large-pore mesh; and a sling that is laser-cut instead of

mechanically cut. That such designs would be safer alternatives is evident from the problems with the existing TVT, as described. In addition, the burch colposuspension used by Dr. Rosenzweig, and the use of a lighter, more absorbable material such would be safer alternatives.

1. Lightweight, large-pore mesh

The TVT is a heavyweight, small-pore mesh.⁴² Dr. Klosterhalfen discussed at length the benefits of lighter-weight, larger-pore meshes. Even though his ultimate issue opinion was cut out, Dr. Klosterhalfen provided ample technical expertise from which the jury could conclude that a lighter-weight, larger-pore mesh would be safer. *See Goodner*, 650 F.3d at 1045 (once expert established technical aspects of case, jury was free to make inference as to ultimate issue).

Dr. Klosterhalfen described how polypropylene meshes can shrink as much 30-to-50% after four weeks in the body, and how reducing the “polypropylene content” leads to a reduction in the inflammatory response and, therefore, in shrinkage.⁴³ Large-pore meshes have a “significant advantage” with regard to shrinkage, which occurs when scar tissue is formed due to the foreign body reaction, causing contraction.⁴⁴ Shrinkage of the mesh then causes pain for the patient, as described by both Drs. Klosterhalfen and Rosenzweig.⁴⁵

Dr. Klosterhalfen also described a study that he conducted for Ethicon, which concluded that “the pore size appears to be of major importance in tissue reaction and for the biocompatibility of mesh structures.”⁴⁶ The larger-pore meshes show less fibrotic reaction, less stiffening, less shrinkage, and therefore, less chronic pain for patients.⁴⁷ Dr. Klosterhalfen also compared the mesh used in the TVT with the material used in Vypro, a lighter-weight, larger-

⁴² Klosterhalfen Dep. at 51:23-25; *see also* Trial Tr. Day 4 (Klinge)

⁴³ Klosterhalfen Dep. at 28:21-29:07; 30:08-20.

⁴⁴ *Id.* at 30:21-31-10.

⁴⁵ *Id.* at 89:8-15 (describing nerve entrapment in scar tissue); Trial Tr. Day 2 at 78:15-79:20.

⁴⁶ Klosterhalfen Dep. at 42:21-43:07.

⁴⁷ *Id.* at 42:06-20.

pore mesh used by Ethicon to treat hernias. He compared two slides and explained how the small-pore Prolene mesh had extensive scar tissue, while the larger-pore Vypro mesh showed fibrotic reaction “that is limited to the mesh.”⁴⁸

Documents and testimony by Ethicon employees further support the claim that lightweight, large-pore mesh is safer. For instance, Dr. Joerg Holste, who has conducted histopathological evaluations for Ethicon for many years, agreed that “leaving less material in the patient’s tissues is important because it will reduce the amount of foreign body reaction.”⁴⁹ He agreed that “another advantage of leaving less mesh material in the human tissue for the patient is that there will be less of an inflammatory reaction.”⁵⁰ Further, he agreed that reducing the inflammatory response helps to prevent the mesh from shrinking.⁵¹ The Vypro mesh used by Ethicon starting in 1998 had 30 percent of the weight and as much as 600% of the pore size in comparison with the Prolene mesh.⁵² Thus, a mesh sling used to treat SUI that had a similar structure to the Vypro would clearly reduce the amount of mesh in the patient’s body.

Similarly, Dr. David Robinson, Ethicon’s former worldwide medical director, agreed that mesh contracture, chronic pain, and painful sex are complications he has seen with the TVT.⁵³ And during the testimony of Dan Smith, a 36-year Ethicon employee, he discussed a presentation regarding Ultrapro, a lightweight, large-pore mesh used by Ethicon in the pelvic floor. He agreed that the document stated that “[c]ompared to heavyweight mesh, reduced mass, large pore size mesh provides advantages such as greater elasticity, less foreign body material implanted

⁴⁸ *Id.* at 81:08-82:07 and Exhibit 1659.

⁴⁹ Holste Dep. at 72:07-11.

⁵⁰ *Id.* at 72:12-17.

⁵¹ *Id.* at 72:18-73:04.

⁵² *Id.* at 87:23-88:04.

⁵³ Robinson Dep. at 354:16-355:07.

and more flexible scar tissue, leading to improvements in patient's quality of life with almost physiological abdominal wall mobility and fewer patient complaints."⁵⁴

All of these documents and testimony describe how a lighter-weight, larger-pore mesh would be a safer alternative design to the TVT. Further, Plaintiff has put on evidence that such a design would have been feasible to Ethicon before Mrs. Lewis's implant in November 2009. Most notably, Ethicon began using lightweight, large-pore mesh as early as 1998, when it introduced the Vypro for hernia repair.⁵⁵ As Dr. Klosterhalfen testified, the same lighter-weight, larger-pore material could be effectively used for the treatment of stress urinary incontinence in the pelvic floor.⁵⁶ Further, Dr. Holste agreed that "even though there was a different application between hernia and the pelvic floor, the principle of using a lighter-weight, larger-pore mesh to reduce patient complications is the same principle."⁵⁷

Ethicon also developed, lighter-weight, larger-pore meshes for use in the pelvic floor. For instance, the Ultrapro mesh is used to treat pelvic organ prolapse, in the same area of the body.⁵⁸ Ultrapro was first used in 2005.⁵⁹ Ethicon has also for many years used Prolene soft mesh, which is a lighter-weight, larger-pore mesh than the TVT, in the Prolift product that is used to treat pelvic organ prolapse.⁶⁰ When asked if there was any reason he could think of that Prolene soft would not be viable to use in a sling used to treat SUI, Dr. Piet Hinoul, worldwide medical director for Ethicon's energy franchise, stated that "[i]t could be."⁶¹ Thus, there is far more than "a scintilla" of evidence from which the jury could conclude that making a sling with

⁵⁴ Smith Dep. at 441:24-442:07, and Exhibit 2172.

⁵⁵ Klosterhalfen Dep. at 20:11-20; 22:13-14.

⁵⁶ *Id.* at 68:21-69:25.

⁵⁷ Holste Dep. at 61:03-09.

⁵⁸ Smith Dep. at 434:11-23.

⁵⁹ Holste Dep. at 37:14-21.

⁶⁰ Hinoul Dep. at 1723:04-19.

⁶¹ *Id.* at 1731:16-25.

lighter-weight large-pore mesh was not only safer, but also feasible to do without substantially eliminating the product's utility. Ethicon was using the material advocated by Plaintiff in several other products before November 2009.

Ethicon actually had a project to try to improve the mesh called "Matrix," with a sub-project called "Scion" that it began in 2007. But Mr. Smith admitted that Matrix was a low priority. Eventually, Scion was jettisoned for "business reasons," but Mr. Smith acknowledged that the "business reasons" were not financial. Thus, they do not indicate a lack of feasibility.

Finally, the analysis above as to causation explains how the safer alternative design would have significantly reduced the risk to Mrs. Lewis, if that is an element of a common-law claim. As described above, there is a greater foreign body reaction with heavyweight, small-pore mesh. This reaction causes fibrotic bridging and scarring, which leads to mesh shrinkage and nerve entrapment, which causes pain and dyspareunia for the patient. As also described above, Mrs. Lewis's explant showed signs of scarring and nerve entrapment. Thus, a jury could conclude that an alternative design, with lighter weight and larger pores, would have reduced her risk of injury.⁶²

2. Laser-cutting the mesh

The second alternative design proposed by Plaintiff is to use laser cutting instead of mechanically cutting the mesh. The analysis as to this proposed alternative design is straightforward, because Ethicon's own documents demonstrate both the feasibility and the benefit of using laser cutting instead of mechanical cutting.

Again, as early as 2005, Ethicon product director Allison London Brown was advocating that Ethicon switch to laser-cutting the TVT, due to complaints from physicians.⁶³ Then Dr.

⁶² See discussion *supra*, Section III(C).

⁶³ Brown May 06, 2005 e-mail, Plaintiff's Exhibit 3162.

Kammerer gave his presentation in 2006, in which he strongly advocated for using laser-cut mesh. He stated that “it is of utmost importance that the mesh is cuttable and that it does not fray or release particles after cutting.”⁶⁴ He also concluded that laser-cut mesh “functions better” than mechanically cut mesh, because there is less fraying, particle loss, roping, and permanent narrowing of the mesh with laser cutting.⁶⁵ Further, Dr. Kammerer’s study compared laser-cut and mechanically cut samples. The study described how “the MCM samples show the degradation of the structure in the mesh in certain areas where, because of particle loss, the knit has opened and a portion of the construction has been lost.”⁶⁶ Not only does the study show that laser-cutting the mesh provided important safety benefits, but it also shows the feasibility of using laser-cut mesh in 2006, because Ethicon actually laser-cut mesh for the study.⁶⁷

Another Ethicon employee, director of post-marketing surveillance Daniel Lamont, discussed a series of e-mails from 2004, in which the conclusion is stated that “[i]f we change the way to cut the mesh to ultrasonic or laser, it seems we can limit the mesh fraying defect significantly.”⁶⁸ He then agreed that laser-cut mesh was designed to address that problem.⁶⁹

In addition, Dr. Rosenzweig testified as to how laser-cutting the mesh helps to “seal the edges” of the mesh.⁷⁰ He described the clinical benefits associated with laser-cutting the mesh, such as reducing the roping, curling, flaking and particle loss associated with the mechanically cut mesh.⁷¹ He further described how the mechanically cut mesh could lead to urinary retention.

⁶⁴ Kammerer Dep. at 190:11-18 and Exhibit 3428, p. 20.

⁶⁵ *Id.* at 214:01-23.

⁶⁶ *Id.* at 233:01-07.

⁶⁷ *Id.* at 233:03-10.

⁶⁸ Lamont Dep. at 12:18-13:14 and Exhibit 3160.

⁶⁹ *Id.* at 13:23-14:01.

⁷⁰ Trial Tr. Day 2 at 85:6-9.

⁷¹ *Id.* at 85:18-25.

Mechanically cut mesh that curls or ropes can “form a point area,” which obstructs the urethra and prevents the free flow of urine.⁷²

Finally, the causation analysis above describes how laser-cutting the mesh would have significantly reduced Mrs. Lewis’s risk. Dr. Klinge observed a loose particle in examining Mrs. Lewis’s explants—exactly the type of loose particle that one often sees flaking off of the edges of mechanically cut mesh.⁷³ Loose particles from the TVT are known to cause pain, including pain during intercourse.⁷⁴ And painful sex was one of Mrs. Lewis’s primary symptoms.⁷⁵ Further, she suffered from urinary retention, and as Dr. Rosenzweig described, mechanically cut mesh causes urinary retention.⁷⁶

For all of these reasons, Plaintiff has put forth more than sufficient evidence that laser-cutting the mesh would have been a feasible safer alternative design that would have significantly reduced Mrs. Lewis’s risk of injury, and that would not have substantially reduced the utility of the product.

3. Burch colposuspension

The third alternative design proposed by Plaintiff is the use of sutures for the burch colposuspension procedure, rather than the use of a sling, for treatment of SUI. Dr. Rosenzweig performs the burch procedure regularly, and he described the process in detail at trial.⁷⁷ In a nutshell, the process involves making an incision and then attaching sutures to ligaments, to create a “hammock” effect that stops the flow of urine.⁷⁸ Even if the Court concludes that the safer alternative design must be a product, the burch procedure does utilize a product,

⁷² *Id.* at 75:17-76:3.

⁷³ Trial Tr. Day 4 at 84:7-13.

⁷⁴ Trial Tr. Day 2 at 100:4-19.

⁷⁵ Trial Tr. Day 5 at 42:3-11.

⁷⁶ Zimmern Dep. at 102:17-25 and Exhibit 6 thereto; Trial Tr. Day 2 at 75:17-76:3.

⁷⁷ Trial Tr. Day 2 at 113:12-114:2.

⁷⁸ *Id.*

specifically sutures. The burch process has been around for 50 years, so it was clearly feasible for Ethicon to make the sutures.⁷⁹

Dr. Rosenzweig also described the benefits of using the burch procedure. For instance, he has seen very little risk of chronic pain with the procedure, and very little risk of dyspareunia.⁸⁰ Studies have shown that the utility of the burch procedure is comparable to the utility of using slings such as the TVT.⁸¹ Based on these factors, Dr. Rosenzweig testified that the burch procedure, using sutures, is a safer alternative to the TVT.⁸²

Finally, there should be little doubt that using sutures and the burch procedure would have significantly reduced Mrs. Lewis's risk, given all of the evidence discussed above that ties her injuries to the TVT—including Dr. Zimmern's direct opinion on that issue.⁸³ Therefore, the Court should conclude that manufacturing sutures for the burch procedure would have been a safer alternative design to the TVT.

4. Use of a lighter, more absorbable material than Prolene

Plaintiff's final argument as to a safer alternative design is that Defendant should have used a lighter, more absorbable material in the TVT, instead of Prolene. A study was done comparing Prolene with a partially absorbable material called PVDF. The result was that Prolene showed degradation, while after four weeks the PVDF was "still normal, it's smooth."⁸⁴ As Dr. Klosterhalfen further testified, degradation causes a chronic inflammatory response.⁸⁵ Such a response, in turn, leads to scarring and other issues described above. The feasibility of using the material in PVDF is seen in a 2007 Ethicon document, discussed by Dr. Klosterhalfen.

⁷⁹ *Id.* at 114:5-6. Ethicon does manufacture sutures, but that fact has not been submitted as evidence.

⁸⁰ *Id.* at 114:18-25.

⁸¹ *Id.* at 110:4-18.

⁸² *Id.* at 117:7-17.

⁸³ Zimmern Dep. at 95:04-18.

⁸⁴ Klosterhalfen Dep. at 72:22-73:18.

⁸⁵ *Id.* at 74:06-75:01.

Ethicon described Pronova, a PVDF material used in other applications, as “the future” of Ethicon’s mesh products.⁸⁶ In addition, the testimony reflects that Pronova was already in use and being experimented on in “the early 2000s.”⁸⁷

As early as 2003, Ethicon was studying whether to replace the TVT with a lighter-weight, larger pore mesh.⁸⁸ Ethicon also worked to some extent on developing a more advanced mesh material in 2007, through a project called “Scion.”⁸⁹ Dan Smith headed that project.⁹⁰ Mr. Smith acknowledged that the budget for projects seeking new mesh materials was low.⁹¹ Eventually, the project was scrapped for “business reasons,” but Mr. Smith testified that those “business reasons” were not financial.⁹²

From this testimony the jury could infer that a different, more absorbable, such as the material already in use in Pronova, would have made the mesh more stable and therefore prevented degradation. This, in turn, would have reduced Mrs. Lewis’s risk of scarring and nerve entrapment, as described above.

CONCLUSION

For all of these reasons, Plaintiff Carolyn Lewis respectfully requests that the Court deny Defendants’ anticipated motion for directed verdict and let the jury decide her bellwether case.

⁸⁶ *Id.* at 244:13-245:12.

⁸⁷ *Id.* at 245:13-20.

⁸⁸ Smith Dep. at 496:11-16.

⁸⁹ *Id.* at 490:02-10.

⁹⁰ *Id.* at 490:07-10.

⁹¹ *Id.* at 540:04-07.

⁹² *Id.* at 491:04-14.

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Respectfully submitted,

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**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
CHARLESTON DIVISION**

IN RE: ETHICON, INC. PELVIC REPAIR SYSTEMS
PRODUCTS LIABILITY LITIGATION

Master File No. 2:12-MD-02327

THIS DOCUMENT RELATES TO:

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CAROLYN LEWIS, ET AL. V ETHICON, INC.

JOSEPH R. GOODWIN
U.S. DISTRICT JUDGE

Case No. 2:12-CV-04301

CERTIFICATE OF SERVICE

I hereby certify that on February 17, 2014, I electronically filed the foregoing document with the Clerk of the court using CM/ECF system which will send notification of such filing to the CM/ECF participants registered to receive service in this MDL.

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